

scoliosis (lateral curvature of the spine), or other conditions.

(b) *Classification*. Class II.

§ 888.3070 Pedicle screw spinal system.

(a) *Identification*. Pedicle screw spinal systems are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(b) *Classification*. (1) Class II (special controls), when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). These pedicle screw spinal systems must comply with the following special controls:

- (i) Compliance with material standards;
- (ii) Compliance with mechanical testing standards;
- (iii) Compliance with biocompatibility standards; and
- (iv) Labeling that contains these two statements in addition to other appropriate labeling information:

“Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impair-

ment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.”

“Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.”

(2) Class III (premarket approval), when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.

(c) *Date PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 888.3.

[66 FR 28053, May 22, 2001]

§ 888.3080 Intervertebral body fusion device.

(a) *Identification*. An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) *Classification*. (1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled “Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.” See § 888.1(e) for the availability of this guidance document.

(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development*